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EXAMINER	
SIMS, JASON M	
ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/624,391	GALLOWAY ET AL.	
	Examiner	Art Unit	
	JASON M. SIMS	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 23-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 23-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 9/22/2008, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-9 and 23-39 are the current claims hereby under examination.

Claim Rejections - 35 USC § 112-New Matter

Response to Arguments

Applicant's arguments, filed 9/22/2008, with respect to the rejection of claims for comprising new matter have been fully considered and are persuasive because of applicants' arguments and pointing to the specification for support. Therefore the rejection has been withdrawn.

Claim Rejections - 35 USC § 112-Enablement-Maintained

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 and 23-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). These factors include, but are not limited to:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The standard for determining whether the specification meets the enablement test was first stated in Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916), and asks if the experimentation needed to practice the invention undue or unreasonable.*

The claimed invention is enabled if any person skilled in the art can make and use the invention without undue experimentation. The focus is on 'undue' rather than on 'experimentation' (*In re Wands*, at 737, 8 USPQ2d at 1404; see also *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988)).

A patent need not teach what is well known in the art (In re Buchner, 929 F.2d 660, at 661, 18 USPQ2d 1331, at 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, at 231 USPQ 81, at 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, at 1463, 221 USPQ 481, at 489 (Fed. Cir. 1984)).

Determining whether claims are sufficiently enabled by the specification is based on underlying findings of fact. *In re Vaeck*, 947 F.2d 488, at 495, 20 USPQ2d 1438, at 1444 (Fed. Cir. 1991); *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, at 576, 224 USPQ 409, at 413 (Fed. Cir. 1984).

The Breadth of the Claims

The claims encompass diagnosing and treating any type of existing manifested and latent malady for diagnostics and treatment, which includes diseases which do not have any medically recognized treatments. Further, the claims encompass a meridian linking, stressing and balancing system. Furthermore, for that, the claims encompass use of "filters", or frequencies, that are presumed to be specific to having a malady or imbalance and/or remedy.

The Nature of the Invention, and the Level of One of Ordinary Skill

As it is with many inventions in the biotechnology arts, the art is multidisciplinary. Applicants' claimed invention relates to a number of core technologies and scientific concepts including internal medicine, acupuncture, electrophysiology, physics, pathology, cardiology and bioinformatics, to name a few. In particular, the claimed invention requires the ability for diagnosing and treating existing manifested and latent maladies within a patient, which includes any malady and accurate analytical techniques (quantitative and qualitative), and the demonstration of data analysis for conclusions that are predictive in disease assessment and treatment for any person.

One of ordinary skill in the art may find that some experimentation is necessary in deciding what type of resistance correlates with what type of disease. Since the invention is drawn to every possible malady an exceptionally large amount of experimentation would be necessary for establishing filters specific for diagnosis and correlating accurate results with particular ailments. Moreover, there is no clear guidance as to what imbalances may be created, ranges of imbalances, or what steps are involved in restoring imbalances. It is also unclear as to how one data access point links all of the internal systems and organs.

The Amount of Guidance, and the Existence of Working Examples

In the *Background of the Invention* (pages 2-5), Applicants summarize concepts in Meridian Stress Assessments and the evolution of electrodiagnosing.

In the *Summary of the Invention* (pages 6-9), Applicants indicate that the invention is directed to a method for advancing alternative medicine treatment methods, and particularly treatment methods utilizing Galvanic Skin Response (GSR) and/or electro-acupuncture by Voll (EAV) devices.

In the *Detailed Description of the Invention*, Applicants summarize the development of the invention along with general ideas about how meridian points work and the correlation between developed maladies and alterations to measurable resistance through Electrodermal Screening. Applicants further summarize the general idea of a working computer, which executes general software instructions for diagnosing and selecting from pre-loaded treatments an optimized treatment.

Applicants continue by alleging that the inventive system is capable of diagnosing and treating any type of malady. Applicant fails to provide any working examples showing data, which correlates any measurable filters or frequencies to an existing malady. One of ordinary skill in the art would not immediately know which "filters," i.e. frequencies correlate with which maladies. Therefore, one of ordinary skill in the art would turn to the specification, which provides no working examples for these correlations nor any data, such as tables, which demonstrate any standards for said correlations. Applicants further allege the ability to diagnose a whole range of ailments as those listed in a table, for example, in Figs. 11, 12, and 15, but do not demonstrate how any of said maladies are diagnosed by having particular "filters" or frequencies. In addition, there is no guidance as to what range of imbalances relate to what maladies. There are no examples of how a single stable reference point links a meridian diagnostic and treatment device or an entire meridian network.

With respect to more specific claims, such as claims 9 and 35, there are neither examples nor guidance on how to arrive at a "meridian linking filter."

Further, there are neither examples nor guidance on how to arrive at a "point stabilizing filter."

Further, there are neither examples nor guidance on how to arrive at a "malady-specific customized filter."

Further, there are neither examples nor guidance on how to arrive at a "product/remedy filter."

Further, there are neither examples nor guidance on how to arrive at a "a prescription constraint filter."

Further, there are neither examples nor guidance on how to arrive at a "homeopathic remedy filter."

With respect to more specific claims, such as claims 27 and 28, there are neither examples nor guidance on how to arrive at said “customized filters.”

With respect to more specific claims, such as claim 36, there are neither examples nor guidance on how to arrive at said “meridian linking filter.”

Further, there are neither examples nor guidance on how to arrive at a "stressing filters."

Further, there are neither examples nor guidance on how to arrive at a "balancing filters."

Further, the examples at paragraph [0015] only address diagnosis of " chemical toxins, allergies, and digestion problems, etc.” and again only restate the idea of diagnosing allergies at paragraph [0113]. However, there are no information on the filters used or on sources of information providing such filters.

When looking to the instant specification for guidance, only general descriptions, which lack any significant detail, are found for teaching one how to use the instant invention. As claimed, one is to first find a stable access point as a reference point on an individual. The next step is to use a filter testing system utilizing customized filters to determine imbalances and diagnose maladies. It is unclear as to what customized filters correlate with which malady and when turning to the instant disclosure only general statements regarding this correlation are found. For example, at paragraph [0113], it is stated “The specific function of the Filter Testing Function is to induce a stress within the body by outputting a customized pre-determined filter corresponding to a specific malady in order to identify and diagnose both existing and latent maladies existing

within the body. Stated differently, each customized filter comprises an assigned malady-specific frequency designed to stress the body with the specific malady to determine if an imbalance is created at the stable point." Furthermore, at paragraph [0115], it is stated that "several pre-determined customized filters may be loaded and stored in the memory databases of the computer system. Each of these customized filters represents or corresponds to one or a combination of maladies that may develop within or infect a patient. As such, the filter database is typically quite large. The customized filters each comprise a frequency that is specific to that filter." Therefore, it is apparent that there are specific correlations between custom filters, or frequencies, which correlate to particular maladies. The instant specification states that the database storing these correlations is quite large indicating that many maladies are diagnosed and treated this way. While these general descriptions are given throughout the instant specification, one of ordinary skill in the art would continue to look for details that would enable a person of skill to be able to operate such a system by, using the real data or correlations stored in said database. As an attempt to disclose a specific example, the specification generally describes a particular malady without disclosing any details such as a possible filter correlation, which is stated in paragraph [0113] "if a patient suffered from allergies, but was unaware of what was causing the allergies, one or more customized filters corresponding or specific to various substances known to cause allergies would be broadcast to the individual, thus stressing the body with each substance." Again, there are no specific examples disclosing such a database with real data to enable one of ordinary skill in the art to know from the instant disclosure, which filters may correlate with which maladies and how to operate such a system of diagnosing such energy disturbances or imbalances. Paragraphs [0163] – [0171] appear as though they will describe in sufficient detail as to enable one of ordinary skill in the art to operate such a system, but fall short with disclosing any real data or specific details and again describe only general functionalities of said system.

Moreover, when looking to the instant disclosure for guidance as to how to determine energy balances and testing, the specification only describes attempts at using skin resistance as an example of a testing point, such as in Fig. 3; Fig. 6-A;

paragraph [0071] disclosing a "diagnostic device interface(s) 100 enable computer device 70 to communicate and exchange information with one or more galvanic skin response (GSR) devices or electro-acupuncture by Voll (EAV) devices, and particularly to one or more meridian linking devices 14 as described herein;" paragraph [0075]; paragraph [0100], which states "the probe or stylus electrically coupled to the device is brought into contact with the skin and caused to probe along the surface of the skin until a data access point is located," etc., which makes it clear that the invention is teaching using skin measurements for practicing the instant invention. Again, there are not found specific data for determining particular frequencies of skin perturbations or skin energy imbalances and correlative maladies.

The State of the Prior Art and the Level of Predictability in the Art

A number of scientific challenges are present in understanding a correlation between energy disturbances and the diagnosis of existing manifested and latent maladies or the restoring of imbalances.

When the instant disclosure fails to enable one of ordinary skill in the art to be able to use or practice such a system, one would next turn to the prior art for guidance to substitute for where the instant disclosure may have fallen short. Any such databases describing real data of filters or frequencies and their correlations to existing or latent maladies has not been found to exist in the prior art. And, the prior art that was found, which one of ordinary skill in the art may attempt to use to operate said system, was found to be very unpredictable and would cause an undue amount of experimentation in order to create such a large database of information.

The prior art does not teach either "filters" or frequencies as being known to be specific to a particular disorder or databases of such frequencies. To the contrary, the prior art is repeat with examples of unpredictability in the art.

With reference to one particular embodiment dealing with allergies, there were numerous prior art references found that disclosed conflicting results and data.

For example, Semizzi et al, at the introduction states that "it is claimed that electrodermal tests would be able to detect the effects or "perturbations' induced on skin

potentials." Semizzi et al. further states that because so few rigorous scientific data are available to validate the procedure, these studies were performed to determine whether the electrodermal devices are able to diagnose the presence of respiratory allergy. The highly trained acupuncture physician stated, at the results, "there was no reproducibility of observations with the same stimulus in the same individual." It was further stated "by looking at individual sequences of measurements, it was impossible to distinguish allergic patients from controls." Moreover, "there was no relation between skin conductivity changes and the type of substance contained in the vial," which were allergens. Semizzi et al. concluded "that the studied bioelectrical method under blind testing, cannot correctly detect respiratory allergy."

Barrett, Stephen, M.D. provides a detailed review on Electrodiagnostics. Barret describes the history of such machines and how they work ranging from companies who produce or sponsor them such as The Occidental Institute Research Foundation and BioMeridian. Moreover Barrett, summarizes a scientific study to compare these electrodiagnostic systems to skin prick tests, which are known as the gold standard, for determining allergic reactions in individuals. Barret's summary states "each participant was tested with 6 items by each of 3 operators in 3 separate sessions, a total of 54 tests per participant. The researchers concluded that Vegatesting does not correlate with skin prick testing and so should not be used to diagnose these allergies." Again, the prior art gives unpredictable results as guidance to one of ordinary skill in the art for using the instant invention and for determining any correlations between filters and maladies.

Lewith et al. also underwent a similar study "to evaluate whether electrodermal testing for environmental allergies can distinguish between volunteers who had previously reacted positively on skin prick tests for allergy to house dust mite or cat dander and volunteers who had reacted negatively to both allergens." Lewith et al. also concluded "the results of the electrodermal tests did not correlate with those of the skin prick tests. Electrodermal testing could not distinguish between atopic and non-atopic participants. No operator of the Vegatest device was better than any other, and no single participant's atopic status was consistently correctly diagnosed. Electrodermal testing cannot be used to diagnose environmental allergies." Again, the prior art gives

unpredictable results as guidance to one of ordinary skill in the art for using the instant invention and for determining any correlations between filters and maladies.

However, with respect to "stable access points" the prior art appears to be unpredictable with respect to establishing meridian and non-meridian "stable access points" points.

For example, Pearson et al. was testing whether skin impedence at each of three acupuncture points or stable reference points is significantly lower than at nearby sites on the meridian and off the meridian. Pearson et al. concluded that none of the three acupuncture points tested has lower skin impedance than at either of the nearby control points. Therefore, Pearson et al. is disclosing the unpredictability with finding differences in impedence between different points on the skin, wherein the instant disclosure, it is stated that these differences exist and one can find a stable reference point, but fail to disclose adequate guidance to enable one of ordinary skill in the art to find said stable access points.

Moreover, Ahn et al. conducted a systematic review of studies directly evaluating the electrical characteristics of acupuncture points and appropriate controls to ascertain or refute the claim that acupuncture points and meridians are special conduits for electrical signals. Ahn et al. at the abstract stated "based on this review, the evidence does not conclusively support the claim that acupuncture points or meridians are electrically distinguishable." Ahn et al. further states that previous studies making such claim "were generally poor in quality and limited by small sample size."

The Quantity of Experimentation

In view of the above, it is the Examiners position that with the insufficient guidance and working examples and in view of unpredictability and the state of art one skilled in the art could not make and/or use the invention with the claimed breadth without an undue amount of experimentation.

Response To Arguments:

Applicant's arguments filed 9/22/2008 have been fully considered but they are not persuasive.

Applicant argues that there is no construction of particular claim terms and no analysis of the claims showing that one of ordinary skill in the art would not know how to make or use the claimed invention.

Applicants' arguments are not found persuasive as the first section titled "The Breadth of Claims" gives a general description of the claim construction as to what the claims read on. Furthermore, throughout the rejection the claims are discussed with regards to how the language is being constructed along with examples from the specification to support particular claim construction.

Applicant further argues that the rejection does not mention claims 1, 2, and 23 and therefore the office has not met its burden to show that the claims are not enabled.

Applicants' arguments are not found persuasive as the rejection is clearly directed to the claimed subject matter of claims 1, 2, and 23 as stated in the rejection “Claims 1-9 and 23-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.” Furthermore, the claimed subject matter of all claims was discussed in each section and with regards to particular variations between independent claims, some specific claim numbers were recited to point to those particular variations. However, the rejection was specific to the claimed subject matter of all claims currently pending and was clearly stated as such in the instant rejection.

Applicant requests that the office refuse to allow its determination in this case to be tainted by the disregard that some persons have expressed in certain publications for the field related to the one in which applicants practice.

Applicants request is not pertinent to the instant office action as the action points out why the instant claims are not enabled and has incorporated particular references, not because they have expressed certain disregard for a particular field, but because the tests performed in the particular references exemplify the particular challenges faced by a person of ordinary skill in the art, which would result in them not being able to practice the instantly claimed invention.

Applicant further argues that none of the references cited in the Office Action discuss filters or frequencies as claimed in the current claim set.

Applicants arguments are not found persuasive because the instant rejection discusses prior art references where frequencies are examined. For example, Semizzi et al. stated "there was no relation between skin conductivity changes and the type of substance contained in the vial," which were allergens. Semizzi et al. concluded "that the studied bioelectrical method under blind testing, cannot correctly detect respiratory allergy."

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

/Michael Borin/

Primary Examiner, Art Unit 1631